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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/085,239	02/27/2002	Simon Ward	674569-2001	1714

20999 7590 07/27/2006

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EXAMINER

ROYDS, LESLIE A

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 07/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/085,239

Applicant(s)

WARD ET AL.

Examiner

Leslie A. Royds

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 May 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 40-43 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 40-42 is/are rejected.
- 7) ☒ Claim(s) 43 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 40-43 are presented for examination.

Applicant's Amendment filed May 2, 2006 has been received and entered into the present application. Accordingly, the specification at pages 18 and 41 is amended.

In view of the foregoing amendments and remarks made herein, the objection to the specification and the rejection of claims 40-42 under 35 U.S.C. 102(b) as set forth at pages 3-4 of the previous Office Action dated November 2, 2005 have each been hereby **withdrawn**.

Objection to the Claims

Claim 43 remains objected to as being dependent upon a rejected base claim, but would otherwise be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim Rejections - 35 USC § 103 (New Ground of Rejection)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out

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the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 40-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burchardt et al. (WO 97/15298, 1997; cited by Applicant on the Information Disclosure Statement filed March 30, 2005).

Burchardt et al. teaches the treatment of acute and chronic inflammatory disorders, such as psoriasis (page 6, lines 1-11; see present claims 40-42), using a glucocorticosteroid, such as carbenoxolone sodium (see present claims 40-42) and an LTD4 receptor antagonist (page 1, lines 4-6 and page 2, lines 3-7).

It is again noted that Burchardt et al. teaches the concomitant use of an LTD4 receptor antagonist with carbenoxolone sodium, but Applicant is reminded that the present claims use the word “comprising”, which is considered open transitional claim language and allows for the use of other components with the active agents recited in the present claims (see MPEP §2111.03[R-2] for a discussion of transitional phrases). Thus, the present claims do not patentably exclude the additional components, such as the LTD4 receptor antagonist of Burchardt et al.

Response to Applicant's Arguments

Applicant's traversal has been carefully considered in its entirety, but fails to be persuasive.

In particular, Applicant asserts that one of skill in the art would have no motivation to look to Burchardt et al. in determining possible treatment for conditions including psoriasis,

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since the document relates to treating inflammatory diseases using an LTD4 receptor antagonist and a glucocorticosteroid. Applicant further submits that without further teaching as to the treatment of hyperproliferative skin diseases, there is no reason why a skilled artisan wishing to treat hyperproliferative skin diseases would turn to a document clearly teaching that the most preferred use of the treatment it describes is for inflammatory airway disorders and, especially, allergic asthma.

However, Applicant is restricting his consideration of the reference solely to that which is preferred and disregards the broader teachings of the reference as a whole. First, Applicant is reminded that the disclosure of a reference is not limited only to that which is preferred or even solely to that which is claimed or exemplified. Applicant is directed to the MPEP at §2123, which states, “*A reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill in the art, including non-preferred embodiments...Disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or non-preferred embodiments.*” (emphasis added) Thus, Applicant’s traversal based on the grounds that the most preferred embodiment of the invention of Burchardt et al. is the treatment of inflammatory airway disorders and allergic asthma and not the treatment of psoriasis is not persuasive because Applicant is not entitled to ignore the broader disclosure of the reference in order to assert patentable distinction over the prior art. Please see *Merck & Co. v. Biocraft Laboratories*, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989).

Applicant further asserts that one of ordinary skill in the art would not have expected a successful outcome from carbenoxolone sodium, since it only appears on the list of “customary

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glucocorticosteroids” and not on the list of “particularly preferred” glucocorticosteroids, and, similarly, that one of ordinary skill in the art would have no reasonable expectation of success in treating psoriasis, since it is not a preferred disease.

However, Applicant clearly is not appreciating the fact that the reference expressly, clearly and unequivocally sets forth the use of a glucocorticoid, i.e., carbenoxolone sodium (page 2, line 7), in combination with an LTD4 receptor antagonist (page 1, lines 4-6), for the treatment of an inflammatory disease, i.e., psoriasis (page 6, line 10). Regardless of the degree of “preference” of the agent or the disease, such does not change the fact that the presently claimed agent is disclosed for use in the presently claimed disease. It is noted once again that a reference is not only limited to that which is preferred. Please see MPEP. §2123 as referenced in the preceding paragraph.

Furthermore, Applicant states at page 7 of the remarks that, “Consequently, one of skill in the art is presented with well over 3,000 possible resulting combinations, with no teachings as to which to select other than to start with beclomethasone and budesonide for the treatment of allergic asthma or other inflammatory airway disorders.” However, it is noted that the comprehensive of the disclosure, particularly in terms of what is disclosed and what is “particularly preferred” out of that disclosure, does not teach away from the entirety of the reference’s teachings as a whole.

The broader teachings of the reference are not negated on the basis of what is more preferable versus what is less preferable or how many combinations are actually encompassed by the teachings. Please reference the MPEP at §2131.02 (see “A Reference That Clearly Names the Claimed Species Anticipates the Claim No Matter How Many Other Species Are Named”),

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which states, "A genus does not always anticipate a claim to a species within the genus. However, when the species is clearly named, the species claim is anticipated no matter how many other species are additionally named. *Ex parte A*, 17 USPQ 2d 1716 (Bd. Pat. App. & Inter. 1990) (The claimed compound was named in a reference which also disclosed 45 other compounds. The Board held that the comprehensiveness of the listing did not negative the fact that the compound claimed was specifically taught. The Board compared the facts to the situation in which the compound was found in the Merck Index, saying that 'the tenth edition of the Merck Index lists ten thousand compounds. In our view, each and every one of those compounds is described' as that term is used in 35 U.S.C. §102(a), in that publication."). Id. at 1718. See also *In re Sivaramakrishnan*, 673 F.2d 1383, 213 USPQ 441 (CCPA 1982)."

Thus, Applicant's arguments that carbenoxolone and psoriasis are not the particularly preferred compound or disorder of the reference or that the comprehensive nature of the disclosure of Burchardt et al. does not set forth the required expectation of success or an enabling disclosure is not found persuasive. Although Applicant asserts that one of ordinary skill in the art would not have expected any likelihood of success in using the combination of carbenoxolone sodium with an LTD4 receptor antagonist for the treatment of psoriasis, Applicant has failed to provide any concrete evidence or persuasive argument other than Counsel's own assertions that such would be the case. Please reference MPEP §716.01(c)[R-2](II), which states, "The arguments of counsel cannot take the place of evidence in the record. *In re Schulze*, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965). Examples of attorney statements which are not evidence and which must be supported by an appropriate affidavit or declaration include statements regarding unexpected results, commercial success, solution of a long-felt need,

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inoperability of the prior art, invention before the date of the reference, and allegations that the author(s) of the prior art derived the disclosed subject matter from the applicant.” (emphasis added)

It is additionally noted that enablement of a prior art reference does not hinge on the presence of working or prophetic examples directed to the discrete combination presently claimed. The presence or absence of working or prophetic examples has no conclusive bearing on the issue of enablement. Working examples are not required to enable an invention. Please reference MPEP §2164.02, which states, “Compliance with the enablement requirement of 35 U.S.C. 112, first paragraph, does not turn on whether an example is disclosed...The specification need not contain an example if the invention is otherwise disclosed in such manner that one skilled in the art will be able to practice it without an undue amount of experimentation. *In re Borkowski*, 422 F.2d 904, 908, 164 USPQ 642, 645 (CCPA 1970).” Insofar as Applicant has failed to produce any evidence or objective showing that what is disclosed in the prior art reference to Burchardt et al. would require undue experimentation and lacks enablement for any other reason than the comprehensive nature of the disclosure and the lack of a working example directed to the express combination of carbenoxolone sodium for psoriasis, Applicant has not provided an evidentiary basis for concluding that the reference is, in fact, not enabled. Such an assertion is, therefore, not persuasive.

For these reasons, rejection of claims 40-42 remains proper and is **maintained**.

Conclusion

Rejection of claims 40-42 remains proper and is **maintained**.

Claim 43 would otherwise be considered allowable, but is objected to for depending from a rejected base claim.

No claims of the present application are allowed.

Applicant's remarks and the submission of the Burchardt et al. reference in the Information Disclosure Statement under 37 C.F.R. 1.97(c) with the fee set forth in 37 C.F.R. 1.17(p) on March 30, 2005 following the first non-final rejection necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609.04(b) and §706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

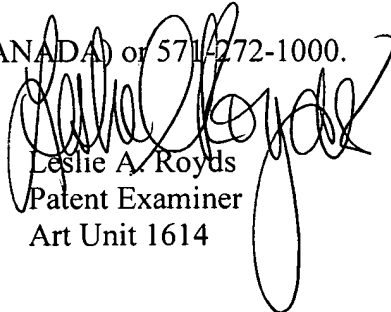
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie A. Royds whose telephone number is (571)-272-6096. The examiner can normally be reached on Monday-Friday (9:00 AM-5:30 PM).


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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571)-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Leslie A. Royds
Patent Examiner
Art Unit 1614

July 11, 2006

 7/23/06
ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER